December 6, 2001

John E. Lynn
The Methanol Institute
800 Connecticut Avenue, N.W.
Suite 620
Washington, DC 20006

Dear Mr. Lynn:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Methanol, posted on the ChemRTK Web Site on, August 3, 2001. I commend The Methanol Institute for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

The Methanol Institute has provided data that satisfy the required SIDS endpoints for physicochemical properties and health effects, although additional information is needed to enhance the robust summaries for health effects endpoints. For estimating transport and distribution of methyl alcohol in the environment, EPA recommends using the Fugacity Level III model. In addition, EPA reserves judgement on the adequacy of aquatic acute toxicity studies pending submission of several required data elements. Furthermore, if the 72-h or 96-h algal toxicity data are unavailable, EPA recommends conducting a new algal toxicity study.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that The Methanol Institute advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@.epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Methyl Alcohol

SUMMARY OF EPA COMMENTS

The sponsor, the American Methanol Institute Testing Group submitted a Test Plan and Robust Summaries to EPA on July 6, 2001, for Methyl Alcohol. EPA posted the submission on the ChemRTK HPV Challenge Web site on August 3, 2001.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. The submitter needs to provide data for Transport and Distribution between environmental compartments using Fugacity Level III model (See Robust Summary comments below).

2. Health Effects Endpoints. All appropriate SIDS level tests have been performed. Additional information on methods and results would assist in the evaluation of the data.

3. Ecological effects. EPA reserves judgement on the adequacy of aquatic acute toxicity studies pending submission of several required data elements. Furthermore, if the 72-h or 96-h algal toxicity data are unavailable, EPA recommends conducting a new algal toxicity study. (see specific comments below).

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE METHYL ALCOHOL CHALLENGE SUBMISSION

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

EPA agrees with the submitter that no further SIDS level testing is required.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

For estimating transport and distribution, EPA recommends using the EQC Fugacity Level III model, which is more realistic than the Fugacity Level I model. EPA recommends using the EQC Fugacity Level III model from the Canadian Environment Modeling Centre at Trent University, which allows full control of data inputs. This model can be found at the following web address: http://www.trentu.ca/academic/aminss/envmodel

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

EPA agrees with the submitter that no further SIDS level testing is required.

Ecological Effects (fish, invertebrate, and algal toxicity)

EPA agrees that several acute ecotoxicity studies are available; however, adequacy of these data could

not be determined because the robust summaries lack several required data elements. (See specific comments below.) In addition, the submitter reported SAR calculations and referred to Appendix B which is missing from the submission.

SPECIFIC COMMENTS ON ROBUST SUMMARIES

Many of the study summaries did not provide sufficient details on methods and results. EPA has provided specific guidance on how to enhance the robust summaries to the standard established in EPA's HPV Challenge Program Guidance at http://www.epa.gov/opptintr/chemrtk/guidocs.htm.

Environmental Fate

In the Robust Summary, under Section 3.3.1 Transport between Environmental Compartments, the submitter needs to provide half-life data for water, air, soil, and sediment.

Health Effects

Acute Toxicity. Information on number of doses, number of animals per dose, dose response of systemic effects (non-primate acute oral studies), and method and results details (non-primate acute inhalation study) is not included.

Repeated-dose toxicity. Information on incidence of effects (non-primate–repeated-dose oral study), number of animals per concentration, animal sex, and dose response (primate–repeated-dose inhalation study) is not included.

In vitro genetic toxicity. Information on experimental details, and positive and negative controls is not provided. In the in vivo genetic toxicity study summary incorrect concentrations are presented in the conclusion section.

Developmental Toxicity (primates). Dosing days and whether or not histopathology evaluation was done is unclear.

Ecological Effects

Fish. The study summaries did not include the following data: water temperature, pH, total organic carbon, dissolved oxygen, water hardness, test substance purity, measured or nominal concentrations, number of replicates, and number of organisms per replicate.

Aquatic Invertebrates. The study summaries lack the following specific information on test conditions: water temperature, pH, total organic carbon, dissolved oxygen, water hardness, test substance purity, measured or nominal concentrations, number of replicates, and number of organisms per replicate.

Aquatic Plants.

Chlorella pyrenoidosa: The NOEC value is higher than the reported EC_{50} value. In addition, the submitter needs to provide the following information: pH, test substance purity, water hardness, closed or open system, amount of head-space, type of algal nutrient media, lighting, measured or nominal concentrations, and temperature.

Phaeodactylum tricornutum: The study summary lacks the following information: pH, test substance purity, water hardness, closed or open system, amount of head-space, type of algal nutrient media, lighting, measured or nominal concentrations, and temperature.

Phaeodactylum tricornutum (second study): The LOEC value is higher than the reported EC_{50} value. In addition, the submitter needs to provide the following information: pH, test substance purity, water hardness, closed or open system, amount of head-space, type of algal nutrient media, lighting, measured or nominal concentrations, and temperature.

Followup Activity

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.